Supreme Court, U.S.
FILED

951367 FEB 26 1996

No. 95- OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1995

MENTOR CORPORATION,

Petitioner,

vs.

ALFRED BINGHAM,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Is a product liability claim arising under state law, alleging that a Class III medical device was defectively designed by its manufacturer, preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a) (1976), where the Food and Drug Administration approved the release of the device to the market under its "510k" regulatory procedure?

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iv

OPINIONS BELOW 2

JURISDICTION 2

STATUTES AND REGULATIONS INVOLVED 2

STATEMENT OF THE CASE 3

A. Proceedings Below 3

B. Source of the Circuit Conflict: 510k and Pre-marketing Approval Procedures Under the Medical Device Amendments 7

REASONS FOR GRANTING THE WRIT 10

CONCLUSION 10

Appendix A:

Opinion of the United States Court of Appeals for the Fifth Circuit (January 5, 1996) ..... App. 1

Appendix B:

Memorandum and Order of the United States District Court for the Southern District of Texas (March 21, 1995) ..... App. 4

Appendix C:

Texts of Statutes and Regulations:

21 U.S.C. § 360(k) ..... App. 23

21 U.S.C. § 360c(f)(3) ..... App. 24

21 U.S.C. § 360c(i) ..... App. 25

21 C.F.R. § 807.81(a)(3) ..... App. 26

TABLE OF CONTENTS – Continued

Page

21 C.F.R. § 807.87.....App. 27

21 C.F.R. § 807.92.....App. 30

TABLE OF AUTHORITIES

Page

CASES

Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3439 (Dec. 22, 1995) (No. 95-1010) 1, 5, 7

English v. Mentor Corp., 67 F.3d 477 (3d Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3469 (Dec. 26, 1995) (No. 95-1034) 1, 7

Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3534 (U.S. Jan. 26, 1996) (No. 95-1214, No. 95-1037) 1, 5, 6, 7, 10

Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995) 7

Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (Jan. 19, 1996) (No. 95-754, No. 95-886) ..... *passim*

Mendes v. Medtronic, Inc., 18 F.3d 13 (1st Cir. 1994) 5

STATUTES & REGULATIONS

21 U.S.C. § 360k ..... *passim*

21 U.S.C. § 360c(f) 3

28 U.S.C. § 1254(l) 2

28 U.S.C. § 1291 2

28 U.S.C. § 1332 4

28 U.S.C. § 1441 4

21 C.F.R. § 801.1, *et seq.* 4

21 C.F.R. § 807.81, *et seq.* 3

TABLE OF AUTHORITIES – Continued

Page

21 C.F.R. § 820.1, *et seq.* 4

21 C.F.R. § 820.5(f) 4

21 C.F.R. § 876.3550(b) 4

OTHER AUTHORITIES

H.R. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990 U.S.C.C.A.N. 6305, 6307) 9

PETITION FOR A WRIT OF CERTIORARI

Mentor Corporation[1] ("Mentor") petitions this Court to issue a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this cause. The court of appeals determined, relying upon its earlier decision in *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3534 (U.S. Jan. 26, 1996) (No. 95-1214, No. 95-1037), that a state law "design defect" claim is not preempted despite the preemption provision found in the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). The Fifth Circuit's findings in this case and in *Feldt* are in direct conflict with the Third and Fourth Circuits' in *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3469 (Dec. 26, 1995) (No. 95-1034), and *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3439 (Dec. 22, 1995) (No. 95-1010). Each of these cases was decided immediately after the Fifth Circuit denied Mentor's petition for rehearing in *Feldt*. This Court has already accepted certiorari in *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (Jan. 19, 1996) (No. 95-754, No. 95-886), a case that presents issues similar to those presented by this petition. Thus, Mentor respectfully requests that this Court grant its petition for certiorari.

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[1] Pursuant to Rule 29.6, Mentor states that it has no parent company and that all of its subsidiaries are wholly owned.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Fifth Circuit (App. 1-3) is unpublished. The Memorandum and Order of the United States District Court for the Southern District of Texas (App. 4-21) in which the court granted summary judgment in favor of Mentor is also unpublished.

JURISDICTION

The court of appeals, whose jurisdiction was invoked under 28 U.S.C. § 1291, entered its judgment on January 5, 1996. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

This case involves the state law preemption provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a) (1976), which states in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter

> included in a requirement applicable to the device under this chapter.

This case also involves 510k pre-market notification regulations promulgated under the Food and Drug Administration, 21 C.F.R. §§ 807.81-807.100, a procedure since codified by the Safe Medical Devices Act, 21 U.S.C. §§ 360(k), 360c(f) and (i) (1990). The relevant provisions of these additional statutes and regulations are printed at App. 23-33.

STATEMENT OF THE CASE

This Court, as noted above, has already granted certiorari in *Lohr*, a case that involves issues similar to those presented in this case. Accordingly, Mentor's statement of the case will be as brief as possible.

A. Proceedings Below

Respondent Alfred Bingham filed this action in state court to recover for damages and injuries he allegedly sustained as a result of his decision to have a Mentor Mark II inflatable penile prosthesis implanted on October 20, 1989. According to his pleadings, Bingham's implant functioned well until June 1992 when he noticed that it would no longer inflate. Bingham initially asserted several causes of action against Mentor including strict liability and negligent marketing, manufacture, and design claims, Texas Deceptive Trade Practices Act ("DTPA"), and breach of warranty claims. App. 4-5. Mentor removed this case to the United States District Court for

the Southern District of Texas on the basis of diversity jurisdiction pursuant to 28 U.S.C. §§ 1332, 1441. *Id.*

The FDA has classified the inflatable penile prosthesis as a Class III medical device, 21 C.F.R. § 876.3550(b), the most stringently regulated class of medical devices. Every aspect of a Class III medical device's manufacture and labeling is governed by the FDA's good manufacturing practices ("GMP"). 21 C.F.R. §§ 801.1-.430, 820.1-.198. In addition to these regulations, Mentor's production of its inflatable penile prostheses is also governed by the FDA's extensive regulations governing "critical" and prescription devices. *See* 21 C.F.R. § 820.5(f).

Before Mentor could release its inflatable penile prostheses to the healthcare market, it was required to obtain FDA approval either under (1) FDA Investigational Device Exemption ("IDE") procedures, (2) the "510k" procedures applicable to a device that the FDA has determined is "substantially equivalent" to those on sale before the adoption of the MDA, or (3) the FDA's premarket approval ("PMA") procedures. *See post*, pp. 8-9.

The prosthesis involved in this case is a Mark II inflatable penile prosthesis which has nearly the same design as Mentor's GFS prosthesis. The FDA first approved the design of the GFS for human use under an IDE granted in 1986, after which Mentor conducted the clinical investigation necessary to test the safety and effectiveness of the device. In 1987, Mentor then submitted a 510k application, which included substantial data on the safety and efficacy of the GFS, much of it gathered during the clinical trials conducted during Mentor's IDE

investigation. After reviewing all the information submitted, the FDA granted the 510k application, and it approved Mentor's release of the GFS for general use in the medical community. Mentor was never requested nor required to submit a PMA for the GFS. App. 8-10.

After the GFS was released to the market, Mentor made minor design changes to it and referred to the modified GFS as the Mark II inflatable penile prosthesis. Mentor did not submit a 510k pre-market notification for the Mark II because its minor design revisions on the GFS did not significantly affect the safety or effectiveness of the GFS' original design. Accordingly, FDA regulations excused Mentor from submitting a separate 510k pre-market notification for the Mark II. The FDA's decision to permit Mentor to release the GFS to the healthcare market covers Mentor's release of the Mark II because of the similarity in the design of the two prostheses. App. 10-11.

After examining the facts and evidence that Mentor submitted in support of its motion for summary judgment, the district court followed the weight of authority from across the country and held that all of Bingham's claims were preempted by Section 360k. App. 20-22.

The Fifth Circuit began its short three-page opinion in this case by noting that it had "already decided the precise issues raised on this appeal in [*Feldt*]." App. 2. In accordance with *Feldt*, the court affirmed the district court's decision to grant summary judgment on Bingham's failure to warn and DTPA claims. *Id.* This holding is also supported by the majority of courts of appeals ruling on this issue, *e.g.*, *Lohr*, 56 F.3d at 1350-52; *Duvall*, 65 F.3d at 399; *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18 (1st

Cir. 1994). The Fifth Circuit reversed the lower court's decision to grant summary judgment on Bingham's design claims on the basis of the earlier panels decision in *Feldt*.[2] App. 2-3.

In *Feldt*, after determining that the plaintiff's manufacturing and marketing claims were preempted, the Fifth Circuit held that Section 360k did not preempt design claims for a device released to the market under the 510k pre-market notification procedures. *Feldt*, 61 F.3d at 436. The court admitted that the 510k procedures required the FDA to determine that the device was as safe and effective as a predicate device. *Id.* Nevertheless, it reasoned that because there are no Class III regulations specifically concerning the safety or efficacy of an inflatable penile prosthesis' design, it was conceivable that the FDA could

> approve an unreasonably dangerous device so long as the device . . . is as safe and effective as the predicate device. 21 U.S.C. § 360c(i). To say that a new device is as safe as its predicate thus indicates nothing, absolutely, about how safe either product is; a new device may be as safe as a predicate device that itself is unreasonably dangerous.

App. 2-3.[3] The Fifth Circuit's decision in *Feldt* accords with the Eleventh Circuit in *Lohr*, but is in direct conflict

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[2] On appeal, Bingham abandoned his manufacturing and warranty claims. App. 2.

[3] The Fifth Circuit's analysis on this point ignores the fact that the FDA is empowered to ban a device from the market if it finds that the device "presents a substantial deception or an unreasonable and substantial risk of illness or injury." 21 C.F.R. § 895.21.

with the decisions of the Third and Fourth Circuits in *English* and *Duvall*. As a result of this circuit split, the FDA's decision to permit a medical device manufacturer to release a device to the market under the 510k pre-market notification procedures preempts design claims brought in the Third and Fourth Circuits, but not in the Fifth and Eleventh Circuits.[4] The conflict between the Fifth Circuit's holding in *Feldt* and the Third Circuit's decision in *English* is particularly ironic because each of the cases involves a Class III inflatable penile prosthesis manufactured by Mentor and released to the market under the 510k pre-market notification procedures. This Court has recently agreed to resolve this conflict of authority by granting certiorari in *Lohr*, 116 S. Ct. 806.

B. Source of the Circuit Conflict: 510k and Pre-marketing Approval Procedures Under the Medical Device Amendments

This circuit conflict arises from differences in the way that Congress treated medical device approval procedures in the MDA, albeit differences that Congress chose not to recognize in the preemption provision of the statute. The opinion of the Third Circuit in *English*, 67

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[4] The Ninth Circuit has recently determined that Section 360k does not preempt any claims brought against the manufacturer of a Class III device that was released to the market after the manufacturer obtained pre-market approval for the device from the FDA. *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995).

F.3d at 479, n.1, provides a useful summary of medical device approval procedures:

> "In adopting the MDA, Congress drew a distinction between devices that were on the market before its passage (and devices 'substantially equivalent' to these devices) and devices marketed after its passage in 1976. Congress realized that it was impracticable to require that devices that were already on the market be withdrawn until they obtained premarket approval from the FDA. *See* 21 U.S.C. § 350e. Instead, Congress directed the FDA to promulgate regulations to allow manufacturers of these devices to move gradually into compliance with the MDA. *Id.* This authority also extended to new devices 'substantially equivalent' to devices on the market as of 1976. *Id.*
>
> "The FDA relied on this distinction as authorization for its 510(k) process. Thus, the FDA has issued regulations, such as 21 C.F.R. § 876, classifying certain preexisting devices (including inflatable penile implants) as Class III devices, but exempting them from immediate premarket approval (by postponing the date the regulations became effective). The FDA also allowed substantial equivalents of these devices to be marketed before obtaining final premarket approval – by completing the 510(k) process. *Id.* at §§ 807.81-807.100. These devices, however, are required to obtain premarket approval in the future. *See* 21 C.F.R. § 870.1-870.3. New devices (i.e. devices not in existence before 1976 or substantially equivalent to such a device) must receive premarket approval before they may be marketed. 21 U.S.C. § 360e(a); 21 C.F.R. § 870.3.

> "With the passage of the Safe Medical Devices Act ('SMDA') in 1990, Pub. L. No. 101-629, Congress explicitly codified these 510(k) procedures. See H.Rep.No. 101-808, 101st Cong., 2d Sess., 1990 U.S.C.C.A.N. 6305, 6319 ('Section 4(b) [of the SMDA] codifies the FDA's current practice regarding the use of the 510(k) procedure for entering the market.'). The current approach is found at 21 U.S.C. § 360c(f)(3), which explicitly allows a manufacturer of a Class III device, for which no final regulation requiring premarket approval has been promulgated, to market the device by complying with the FDA's 510(k) notification process. Similarly, the SMDA codified the FDA's definition of substantial equivalence. *See* 21 U.S.C. § 360c(i)(1)(A). Because Congress in the SMDA codified FDA procedures in place at the time the device implanted into English was approved by the FDA pursuant to the 510(k) process, we make reference to its provisions in determining the extent to which the FDA has regulated the device." [Italics in original.]

Thus, while it is true that there are differences in approval procedures under the statute, the plain language of 21 U.S.C. § 360k(a) confirms that Congress chose not to recognize these differences when it came to write the preemption provision. The vice of the decision below, and that of the Eleventh Circuit in *Lohr*, is that both courts effectively rewrote Section 360k(a) as if Congress had not said "*any* requirement . . . which relates to the safety . . . of the device," but instead had said, "any stringent requirement imposed under the PMA process."

REASONS FOR GRANTING THE WRIT

1. This Court granted certiorari in *Lohr*, to consider whether a state law claim is preempted by federal law when the plaintiff alleges injury caused by the defective design of a medical device. This petition tenders the same issue.

2. The Fifth Circuit's decision in this case is based on its prior decision in *Feldt*, in which the court reached a result that is substantially similar to *Lohr*. Both a petition and cross-petition for certiorari were filed in the *Feldt* case. Both petitions are pending before this Court, Nos. 95-1037, 95-1214. Mentor's petition should be granted for the same reasons that this Court granted certiorari in *Lohr*, to resolve a mature circuit conflict on a question of importance, *viz.*: whether the 510k pre-market notification process of Class III medical devices triggers preemption of design defect claims under 21 U.S.C. § 360k(a).

CONCLUSION

The petition for a writ of certiorari to the United States Court of Appeals for the Fifth Circuit should be granted.

Dated: February 23, 1996

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 95-20288

ALFRED BINGHAM,

Plaintiff-Appellant,

versus

MENTOR CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Texas
(CA-H-94-0025)

(Filed Jan. 05, 1996)

Before JONES, EMILIO M. GARZA, and BENAVIDES, Circuit Judges.

Per Curiam[1]:

Appellant Alfred Bingham ("Bingham") appeals the district court's judgment that all of his claims against Mentor Corp. ("Mentor") were preempted as a matter of law by § 360k of the Medical Device Amendments of the Food, Drug & Cosmetics Act and the court's grant of

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[1] Pursuant to Local Rule 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in Local Rule 47.5.4.

summary judgment to Mentor on that ground. Because this court has already decided the precise issues raised on this appeal in *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), we affirm the grant of summary judgment in part, reverse in part, and remand.

DISCUSSION

Although Bingham raised several claims against Mentor in the district court for injuries he allegedly suffered when his Mentor Mark II inflatable penile prosthesis failed, he asserts on appeal only claims for design defects, a failure to warn, and for violations of the Texas Deceptive Trade Practices Act ("DTPA").

The district court properly granted summary judgment to Mentor against Bingham's claims for a failure to warn and for violations of the DTPA. As this court recently explained in *Feldt*, § 360(k) preempts claims that "are grounded on allegations of inadequate warnings or labeling. The district court did not err in finding [such a] failure-to-warn claim [preempted.]" *Feldt*, 61 F.3d at 436. Likewise, because Bingham's only DTPA claim "relate[s] to general marketing or advertising of the device, [it is] preempted by the FDA's explicit regulations on labels and warnings." *Feldt*, 61 F.3d at 438.

Although it properly granted summary judgment on Bingham's claims for failure to warn and for violations of the DTPA, the district court erred when it did so for Bingham's design defect claim. This court in *Feldt* refused to hold such claims preempted because

> [a]t the very least, then, the nexus between the state and federal requirements is much weaker

> with respect to design defects than it is with respect to manufacturing and labeling, and we find this nexus inadequate to justify the displacement of state law regarding defective design.

Feldt, 61 F.3d at 438. Consequently, Bingham's state law claims against Mentor for defective design of his penile prosthesis are not preempted by § 360(k) and survive a summary judgment on that basis. As defense counsel are aware, one panel of this court cannot overrule a prior panel decision.

CONCLUSION

For the foregoing reasons, the district court's grant of summary judgment is **AFFIRMED** in part, **REVERSED** in part, and **REMANDED.**

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ALFRED BINGHAM, Plaintiff	§	
VS.	§	CIVIL ACTION NO. H-94-25
MENTOR CORPORATION, Defendant	§	

MEMORANDUM AND ORDER GRANTING SUMMARY JUDGMENT

(Filed Mar. 22, 1995)

Pending before the Court in the above referenced action, alleging injuries caused by implantation of a defective inflatable penile prosthesis[1] are manufacturer/ Defendant Mentor Corporation's motion for summary judgment (instrument #18) and motion for protective

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[1] Plaintiff asserts that Mentor changed the Mark II penile prosthesis from the earlier two-piece GFS model, which had been placed into distribution with FDA approval as a device "substantially equivalent" to those on the market prior to the date of the enactment of the Medical Device Amendments, May 28, 1976. *See* discussion *infra*. Plaintiff claims that the modified Mark II model was not properly approved before marketing. Plaintiff had a Mark II prosthesis implanted on October 20, 1989 to treat erectile impotence. In June 1992, he complains, his prosthesis would no longer inflate because the fluid leaked. He has not had it removed because he cannot afford such a procedure.

order until the Court rules on the motion for summary judgment (#17).

Defendant contends that Plaintiff Alfred Bingham's claims, all grounded in state law,[2] are completely pre-empted under Section 360k of the 1976 Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 360c-360l. The MDA was "intended to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States." S. Rep. No. 33, 94th Cong., 2d Sess., at 1071 (1975). Defendant notes that Congress also intended the MDA to protect manufacturers of medical devices from state regulation over and above those regulations imposed by the federal government, because the state regulation would create an undue burden on interstate commerce. H.R. Rep. No. 853, 94th Cong., 2d Sess. p. 45 (1976); *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994). The statute's express, broad preemption provision, § 360k, prohibits additional state requirements:

> **(a) General Rule**
>
> . . . no State or political subdivision of a State may establish or continue in effect with respect

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[2] Plaintiff asserts claims for violation of the Texas Deceptive Trade Practices Act, strict liability, breach of implied and express warranties, and negligence, as well as for failure to obtain approval from the Food and Drug Administration before releasing its Mark II inflatable penile prosthesis.

> to a device intended for human use any requirement –
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The FDA has interpreted this preemption provision as follows:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

Defendant emphasizes that the Fifth Circuit has found § 360k applicable to, and preemptive of, civil suits against manufacturers of medical device [sic] where " . . . A state cause of action . . . (1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA." *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.) (granting

summary judgment to manufacturer of anti-wrinkle collagen on the basis of § 360k)[3], *cert. denied*, 114 S. Ct. 86 (1993). Defendant points out that the decision in *Stamps*, 984 F.2d at 1424, relied on the statutory language of § 360k and on the FDA's interpretation, located at 45 Fed. Reg. 67236, 67238 (1980): "Congress established an [sic] specific standard of preemption . . . [in section 360k] . . . is not restricted State requirements that directly conflict with Federal law, but rather extends to requirements that are different from, or in addition to, any requirement applicable to the device under the act."[4]. *See also King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993). *See also* 21 C.F.R. § 808.1(d)(6)(i) (state regulations conflicting with general regulations governing the records device that manufacturers are required to maintain are preempted). So are general state prohibitions on the manufacture of adulterated or misbranded devices if they create "a special labeling requirement different from, or in addition to, a Federal requirement established under the act." 21 C.F.R. § 808.1(d)(6)(ii). Moreover, Defendant contends that the preemption applies even if the FDA has not approved the device's design. Therefore Defendant insists that imposition of tort liability against it here would create regulations different from or in addition to existing federal regulations governing inflatable penile prostheses. The

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[3] The Fifth Circuit based its decision on *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992).

[4] The FDA's interpretation of the statute is entitled to "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *Stamps*, 984 F.2d at 1421 n.2.

FDA classifies inflatable penile prostheses as Class III[5] medical devices, a category which encompasses devices that provide the greatest benefit and the most risk to people and are therefore subject to the most extensive regulation by the FDA. 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 860.3(c)(3) and § 876.3350. It is also classified as a "critical device" for some purposes; a "critical device" is one "intended for surgical implant into the body . . . and whose failure to perform when properly used . . . can be reasonably expected to result in significant injury to the user." 21 C.F.R. § 820.5.

Defendant explains that when it first tried to market the Mark II prosthesis, it applied for and received an Investigational Device Exemption ("IDE")[6] for a two-piece inflatable prosthesis, then known as GFS, in compliance with 21 U.S.C. § 812, to demonstrate the safety and

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[5] The MDA classifies all medical devices intended for human use into three categories. Class I encompasses devices that do not require extensive regulation to protect the health and safety of the public. Class II is composed of more complicated devices requiring more regulation.

[6] There are two exceptions to the rule that a Class III device must undergo premarket approval before being distributed to the public. The IDE allows the device to be clinically tested on people before premarket approval is sought. In the instant case although Plaintiff was not an IDE recipient of a prosthesis, Defendant raises the IDE review as one aspect of his compliance with the MDA in developing the Mark II. The other is by obtaining a determination that a device is "substantially equivalent" (*See infra* and n.7) to one on the market prior to May 28, 1976. In the latter case, no premarket approval is required unless the FDA issues a regulation requiring that specific device to undergo review. *See* § 360e.

effectiveness of the device in clinical use. The IDE application contained extensive information on labeling and clinical testing procedures, chemical and biological tests, package data sheet information, and operating, inspection, and manufacturing procedures. The application was approved and Defendant accordingly conducted clinical trials to test the safety and effectiveness of the two-piece prosthesis.

At the time, FDA did not require any inflatable penile prosthesis to undergo a premarket approval process. 21 C.F.R. § 876.3350. The FDA did require the manufacturer to submit a premarket notification of its intent to market the device at least 90 days before marketing it. 21 C.F.R. § 807.81. The process, sometimes designated as a "Section 510k Premarket Notification," requires the manufacturer to demonstrate that the device is "substantially equivalent"[7] to other products on the market as of the effective date of the MDA, May 28, 1976. To do so, the manufacturer must persuade the FDA that the device does not create any safety or effectiveness considerations in addition to those posed by the predicate device. *See* 21 C.F.R. § 807.81(a)(3)(i) (section 510k determination necessary for change in original device that could affect its safety or effectiveness). Because Class III devices pose the greatest

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[7] Defendant quotes the definition of "substantial equivalence," a question for expert judgment, from Richard M. Cooper, *Clinical Data under Section 510k*, 42 Food, Drug Cosm. L.J. 192, 195 (1987): "To be substantially equivalent, two devices need not be physically identical or even similar, but they must serve substantially the same purposes and their performance of those purposes must be substantially equivalent in safety and effectiveness."

risk to human safety, the 510k Premarket Notification Process is more rigorous and the FDA conducts a more searching review of the submitted documentation than the review for Class I or II devices. Regulations require a manufacturer who intends to market a device that has undergone a significant change from a predicate device to submit supporting data to "show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device." 21 C.F.R. § 807.87(g). On June 9, 1987, Defendant submitted a Section 510k Premarket Notification for the GFS two-piece inflatable prosthesis, which included all requisite information and the IDE documentation and results of the clinical trials. In a letter dated August 26, 1987 the FDA stated that it found the GFS two-piece prosthesis to be substantially similar to devices marketed prior to the effective date of the MDA, thereby permitting Defendant to market it, subject to the other extensive regulations governing the manufacture of penile prostheses.

Defendant did not submit a Section 510k Premarket Notification for the Mark II because it considered the Mark II's design modifications[8] to be minor and not

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[8] Defendant explains that the prosthesis has two major components: a Resipump, which is place inside the male scrotum and the cylinders that are inserted into the penis. The Resipump is connected to the cylinders by pieces of tubing. To achieve an erection, the implant recipient squeezes the Resipump, forcing a solution stored in it into the cylinders. To deflate the penis, a release valve on the Resipump is pressed and the fluid returns to the Resipump. The Mark II differs from the earlier GFS in not having tubing connectors joining the tubing from the Resipump to the cylinders.

significantly altering the safety or effectiveness of the two-piece GFS. Defendant argues that therefore it was not required to submit a separate Section 510k Premarket Notification for the Mark II. 21 C.F.R. § 807. Defendant further insists that the FDA's determination that the GFS was substantially equivalent to a device on the market prior to the enactment of the MDA also covers the Mark II. Defendant did comply with an FDA directive that each device manufacturer determine whether the alteration in the device's design requires a separate Section 510k Premarket Notification when it expressed its reasons for not submitting a separate notification in a document referred to as an "In Lieu of 510k." FDA, 510k Regulatory Requirements for Medical Devices, p. iv ("The final rule on 510(k) advises manufacturers that it is their responsibility to determine whether a proposed change or modification requires 510(k) review by the FDA.").

Defendant insists that the imposition of liability under Texas product liability law would impose a regulation on Mentor's release of the device to the market that would be in addition to and different from the regulations created by the FDA. *See Mendes v. Medtronic,* 18 F.3d 13 (1st Cir. 1994).

As for the device's labeling, Defendant contends that its Product Information Data Sheets ("PIDs") with appropriate warnings[9] included in the Mark II complied with

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[9] Specifically the PIDs provided,

> Any patient undergoing a surgical procedure is subject to possible unforeseen operative and postoperative complications. Potential reactions and complications should be discussed with and

the many specific federal regulations. Plaintiff alleges that Defendant failed to provide information about possible complications or mechanical failures of the Mark II. Defendant insists that imposing liability on it under Texas law for inadequate labeling and warning would also constitute a regulation in addition to, differing from, or possibly conflicting with FDA regulations governing the labeling or prescription and critical devices and applying to the Mark II. *Mendes*, 18 F.3d at 13. It notes that FDA regulations allow it to address warnings about the device to qualified healthcare providers. 21 C.F.R. § 801.109.

Furthermore, the FDA has approved of Good Manufacturing Practices ("GMP") that govern the production, storage, and distribution of medical devices. 21 C.F.R. §§ 820.1 *et seq*. The FDA has also enacted GMP regulations to apply to "critical devices" such as inflatable

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> understood by the patient prior to surgery. Mentor Corporation relies on the surgeon to advise the patient of all potential risks and complications associated with the proposed surgical procedure and device, including providing a comparison of the risks and complications of alternative procedures and devices. Patients should be advised that penile implants should not be considered lifetime implants due to the inherent nature of penile implants, implant procedures and potential individual physiological reactions.

Moreover the PIDs stated, "This is a mechanical prosthesis which, like any mechanical device, can wear out, be subject to user misuse, malfunction and require replacement." They also warned, "Mechanical complications with this prosthesis may include malfunction of the Resipump, cylinder, tubing, or connector leaks. Patients should be informed prior to surgery that a replacement procedure may be necessary."

penile prostheses. 21 C.F.R. § 820.5(f). Defendant in detail discusses the requirements for organization, personnel, and physical facilities, component parts, manufacture of the device, inspection, distribution and storage, and records. It maintains that any verdict based upon Plaintiff's strict liability product claims, negligence, breach of warranty, or DTPA would be in addition to and different from these exhaustive GMP requirements. *Mendes*, 18 F.3d 13.

Defendant also cites and discusses numerous court decisions holding that state tort and product liability claims against a manufacturer of a Class III medical device marked under a substantial equivalence finding are preempted by section 360k. Defendant further points to a number of federal courts which have concluded that section 360k preempts claims against the manufacturer of Class III medical devices that have been released to the market under a Section 510k Premarket Notification.

Defendant also argues that Plaintiff's claims that the Mark II was not properly approved by the FDA before being marketed to physicians and hospitals are preempted by the MDA because Defendant decided not to submit a Section 510k Premarket Notification. As indicated above, Defendant maintains that it was not required to do so and that it has complied with all applicable federal regulations in marketing and the FDA's directive to assume the responsibility of determining whether an innovation in a device's design requires the manufacturer to submit a separate Notification.

Defendant further maintains that Plaintiff does not have standing to assert a claim for violations of the FDA

or the MDA, which do not provide a private party with a cause of action for damages, and therefore he cannot recover. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542-43 (3d Cir. 1994); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976); *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33 (M.D. Pa. 1989), *aff'd*, 902 F.2d 1558 (3d Cir. 1989); *see also Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 819 (1986). Plaintiff cannot assert a state law cause of action upon a breach of the MDA because such a claim would be preempted by section 360k for imposing an additional or different regulation on the manufacture of a medical device. *Gile*, 1994 WL 160861 at 4; *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1022 (E.D. Mich. 1993).

Plaintiff opposes the motion for summary judgment, arguing that his state-law claims are not preempted because there are no counterpart federal regulations or requirements applicable to the device in dispute. While the GFS entered the market because it was "substantially equivalent" to a device in distribution before May 28, 1976, he emphasizes that neither the GFS nor the Mark II went through the detailed and rigorous requirements of the premarket approval process. He contends that the FDA's interpretation of the MDA, *supra*, and the regulations issued under it indicate there is no preemption here. He further maintains that the general controls and procedural requirements of the substantial equivalence process should not preempt his claims and leave him without remedy. He agrees that if the Court determines that all of his claims are preempted, discovery is unnecessary. If the Court finds that any claims are not preempted however, Plaintiff has also asserted that Defendant failed

to comply with limited FDA rules applicable to the Mark II and requests a Rule 16 scheduling conference and adequate discovery on this issue.

Plaintiff insists that his state law claims are not preempted for several reasons. The GFS was marketed under the FDA letter of August 26, 1987, which not only revealed a determination by the FDA of substantial equivalence determination but also warned, "This letter does not in any way denote official FDA approval of your device or its labeling." In contrast, argues Plaintiff, the Mark II was marketed under what Defendant terms "In Lieu of 510k," a phrase not found in the MDA or FDA regulations. Plaintiff contends that the Mark II was released for commercial distribution in January 1989, before the March 6, 1989 "In Lieu of 510k" was prepared. Moreover it was not filed with the FDA but merely exists as a memo in Defendant's files. Furthermore, argues Plaintiff, because Defendant failed to comply with the limited federal controls under MDA applicable to its device in not filing a Section 510k Premarket Notification, the state law claims are not preempted and "common law liability would impose no additional substantive requirements." *Dal Porto v. Telectronics Pacing Systems, Inc.*, Civ. No. S-93-0720 (E.D. Cal. August 31, 1994).

In support of its nonpreemption stance, Plaintiff cites *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 1, 837 P.2d 1273 (Haw. 1992) (holding that under the language of the statute, the FDA's interpretation of the statute, and the intent of Congress, plaintiff's state-law claims regarding the design defect of a class III pacemaker, which entered the market after a finding of substantial equivalence, were not preempted). Plaintiff points out that while the

Fifth Circuit has found preemption of claims involving Class III medical devices that survived the premarket approval process in *Stamps*, 984 F.2d 1416, 1421, the appellate court there distinguished premarket approval and 510k notification in the opinion. Plaintiff argues that *Stamps* should not be extended to 510k products, marketed under a far less rigorous standard than that required by the premarket approval process. Plaintiff notes that a premarket approval application must be denied if there is an insufficient showing of safety and effectiveness, while in the 510k submission, the focus is on the device's substantial equivalence to a product in the market before May 28, 1976: any inquiry into safety and effectiveness under 510k is limited to whether the substantially equivalent device is as safe and effective as the predicate device. Furthermore, Plaintiff complains, classification as a Class III device does not automatically impose premarket approval requirements, which still have not been imposed by any FDA regulation on inflatable penile prostheses. Because the FDA never issued final regulations applicable to the inflatable penile prosthesis, Plaintiff maintains that there is no preemption because the device was marketed under a 510k submission and was subject only to general controls. *See, e.g., Lamontagne v. E.I. Du Pont de Nemours and Co., Inc.*, 834 F. Supp. 576, 584-85 (D. Conn. 1993) (though TMJ implant was subject to general controls, there were no regulations specific to the device itself and therefore no preemption of state law claims). *See also Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) (design claims are not preempted as to Class II menstrual tampons). Plaintiff contends that *King*, 983 F.2d at 1138 (holding the premarket approval process

for a collagen product was a requirement invoking preemption), and *Mendes*, 18 F.3d 13[10] (holding that Congress intended that state common-law claims related to the safety and effectiveness of a Class III pacemaker are preempted), should not control here. It reiterates that all devices be subject to general controls but FDA's interpretation of the preemption provision requires preemption of state law claims only where there are *specific* federal law requirements under the MDA. Plaintiff insists that general requirements do not preempt his claims.

Plaintiff also notes that because he was not implanted under an IDE, none of the safeguards in that process were applicable to him.

In a supplemental response, Plaintiff further cites *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994), in which the Fifth Circuit interpreted the language of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b): "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." The Fifth Circuit, relying on *Worm v. American Cyanamid Co. ("Worm I")*, 970 F.2d 1301 (4th Cir. 1992), held that FIFRA does not preempt state laws that do not impose any different or additional labeling requirements. In the second *Worm* case, the Fourth Circuit stated, "If a state elects to recognize that a breach of a FIFRA-created duty forms the basis for a state remedy, we have held that it is permitted

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[10] Plaintiff notes that *Mendes'* analysis has already been rejected in *Oja v. Howmedica, Inc.*, 1994 WL 122336 (D. Colo. Apr. 1, 1994).

to do so by 7 U.S.C. § 136v(b)." *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993), *citing Worm I*, 970 F.2d at 1308. Plaintiff argues by analogy that since the MDA and FIFRA use similar language, i.e., "different from, or in addition to," any MDA-created duty may also form the basis for a state remedy. He represents that in response to a Freedom of Information Act request, he has received documents that reflect numerous violations of the general controls under the MDA, especially reporting requirements for device failures.[11]

After reviewing the record and the applicable law, this Court concludes that Defendant is correct and that Plaintiff's state-law claims are preempted as a matter of law by the MDA.

First the Court concludes from the extensive review of requirements, explanation of the steps it took, and documentation presented by Defendant regarding the manufacture, evolution, testing and detailed submissions to the FDA, and marketing of its inflatable penile prosthesis, that it clearly obtained approval from the FDA. After obtaining an IDE and submitting a 510k premarket notification, the August 26, 1987 letter from the FDA after a review of Defendant's materials and documentation indicating that the FDA had determined that the GFS was substantially equivalent to pre-MDA devices constituted approval to distribute the GSF [sic] prosthesis to the public, subject to the general regulations including the GMP. Defendant had the right to determine whether the

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[11] The Court notes that Plaintiff also has not pleaded violations of MDA requirements in his amended complaint.

Mark II required an additional 510k review and determined that a separate notification and review were not necessary. 21 C.F.R. § 807. Plaintiff has not shown that the "In Lieu of 510k" memorandum needs to be prepared at the time such a determination is made. Moreover Plaintiff received his prosthesis after the approval had been obtained and the memorandum finding separate notification unnecessary was prepared.

In *Stamps* the Fifth Circuit, emphasizing the Class III regulatory structure, under the literal language of the express preemption provision, § 360k, of the MDA, held that for devices that went through the premarket approval practice,

> [s]tate requirements pertaining to the safety or effectiveness of a device, or to any other matter included in a requirement made applicable to the device by the MDA, are preempted whenever they are different from, or in addition to, any requirement imposed upon the devise [sic] under the MDA. . . . State tort causes of action – to the extent they relate to safety, effectiveness, or other MDA requirements – constitute requirements "different from, or in addition to" the Class II process; they are, therefore, preempted.

Plaintiff has argued that the device in *Stamps* underwent the greater scrutiny in the premarket approval process than the device here, which at best was given with only substantial equivalence approval. He relies on *Larsen*, 74 Haw. at ___, 837 P.2d at 1282, with its holding opposite to *Stamps'*: the Hawaii Supreme Court ruled that "the statutes and regulations governing [even] premarket approval set forth general procedural requirements and, therefore, do not trigger a preemption analysis under

§ 808.1(b)"[12] where there are "no specific statutes or regulations applicable to the particular device in question. . . . " Nevertheless, the Fifth Circuit, which controls here, did not distinguish between the premarket approval and 510k submission in regard to preemption in *Stamps*. The plaintiff there argued that "the MDA preempts state law only to the extent that the state mandates a similar [premarket approval] process." *Id.* at 1423. The Fifth Circuit disagreed and wrote, "[State premarket approval] processes are preempted in addition to any other state requirements relating to safety or effectiveness or any other MDA requirement established for the device." *Id.* It further stated that MDA's preemption applies to "any requirement imposed upon the device" and "a specific requirement applicable to a particular device." 984 F.2d at 1424. While less stringent, the 510k review imposes specific requirements upon the manufacture of the device before it can obtain a determination of substantial equivalence by the FDA, and therefore Plaintiff's state law tort claims are preempted.

The Court points out that the First Circuit has held that state law tort claims against a manufacturer of a Class III medical device distributed to the public pursuant to a substantial equivalence finding by the FDA are preempted. *Mendes*, 18 F.3d 13; *King*, 983 F.2d 1130. *See*

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[12] Section 808.1(d) provides that state and local requirements are preempted "only when the [FDA] has established specific counterpart regulations, or there are other specific requirements applicable to a particular device under the act. . . . "

also English v. Mentor Corp., NO. Civ. a. 93-2725, 1994 WL 263353 (E.D. Pa. June 13, 1994).

As for Plaintiff's claims of breach of warranty and violations of the DTPA, they are preempted by MDA's labelling requirements and GMP. *Stamps*, 984 F.2d at 1422 n.5; *Mendes*, 18 F.3d at 18-20. Plaintiff's claim for strict liability is also preempted because it would impose requirements related to safety and effectiveness of the product, since a successful claim would require the manufacturer to redesign the device, remove it from the market, and require a court to controvert the FDA's determination of safety. *King*, 983 F.2d at 1135.

Accordingly, the Court

ORDERS that Defendant's motion for summary judgment is GRANTED on grounds that Plaintiff's claims are preempted by the MDA. Defendant's motion for protective order is therefore moot.

SIGNED at Houston, Texas, this 21st day of March, 1995.

/s/ Melinda Harmon
MELINDA HARMON
UNITED STATES
DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ALFRED BINGHAM, Plaintiff	§	
VS.	§	CIVIL ACTION NO. H-94-25
MENTOR CORPORATION, Defendant	§	

FINAL SUMMARY JUDGMENT

(Filed Mar. 22, 1995)

Pursuant to the memorandum and order signed on this day, the Court

ORDERS that FINAL SUMMARY JUDGMENT is GRANTED in favor of Defendant Mentor Corporation against Plaintiff Alfred Bingham. Plaintiff shall take nothing and shall bear all costs of court.

THIS IS A FINAL JUDGMENT.

SIGNED at Houston, Texas, this 21st day of March, 1995.

/s/ Melinda Harmon
MELINDA HARMON
UNITED STATES
DISTRICT JUDGE

APPENDIX C

21 U.S.C. § 360(k) (1994)

§ 360. Registration of producers of drugs or devices

. . . .

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe) –

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

21 U.S.C. § 360c(f)(3)

§ 360c. Classification of devices intended for human use

. . . .

(f) Initial Classification of certain devices

. . . .

(3) If a manufacturer reports to the Secretary under section 510(k) [21 USC § 360(i)] that a device is substantially equivalent to another device

> (A) which the Secretary has classified as a class III device under subsection (b),
>
> (B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and
>
> (C) for which no final regulation requiring premarket approval has been promulgated under section 515(b) [21 USC § 360e(b)],

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) [21 USC § 360(k)] a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 510(k) [21 USC § 360(k)] report is being made and which has not been submitted to the Secretary under section 519 [21 USC § 360i]. The Secretary may require the manufacturer to submit the

adverse safety and effectiveness data described in the report.

21 U.S.C. § 360c(i)

§ 360c. Classification of devices intended for human use

. . . .

(i) Substantial equivalence.

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l) [21 USC § 360j(l)], the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device –

(i) has the same technological characteristics as the predicate device, or

(ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant

change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 510(k) [21 USC § 360(k)] respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

21 C.F.R. § 807.81(a)(3) (1995)

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device

intended for human use which meets any of the following criteria:

. . . .

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, i.e., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

. . . .

21 C.F.R. § 807.87 (1995)

§ 807.87 Information required in a premarket notification submission

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submissions.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basics for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification

submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(k) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

21 C.F.R. § 807.92 (1995)

§ 807.92 Content and format of a 510(k) summary

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is

intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

(6) If the device has the same technological characteristics (i.e., design material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a

discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

(c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."